K111254

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AUG 2 2 2011

510(k) SUMMARY

Sponsor/Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, California 94025
Contact Person:	Kim Ky Sr. Regulatory Affairs Specialist Phone: (650) 687-4473 Fax: (650) 687-4449
Date of Submission:	August 11, 2011
Device Trade Name:	Relieva Solo Elite Sinus Balloon Catheter
Common Name:	Sinus Balloon Catheter
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Classification Name:	Ear, nose, and throat manual surgical instrument
Product Code:	LRC
Predicate Devices:	Relieva Sinus Balloon Catheter (K073041) Xpress Multi-Sinus Dilation Tool (K102003)
Device Description:	The Relieva Solo Elite Sinus Balloon Catheter is a flexible catheter that is intended to dilate sinus ostia. The shaft allows for inflation of the sinus balloon and permits the passage of a sinus guidewire or sinus illumination system to facilitate access to the target sinus ostia. A hypotube is incorporated on the proximal end to provide rigidity during insertion through a sinus guide catheter. The subject device also has the capability to irrigate the sinus through the distal tip and three side holes on the distal end.
Indications for Use:	The Relieva Solo Elite Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedure and to facilitate diagnostic procedures. For children aged 17 and under, the Relieva Solo Elite Sinus Balloon Catheter is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedures and to

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	facilitate diagnostic procedures.
Technological Characteristics:	The Relieva Solo Elite Sinus Balloon Catheter is a device that allows for dilation of sinus ostia with the added capability to irrigate. Dilation is achieved via a non-compliant balloon located on the distal end of the device.
Performance Data:	The Relieva Solo Elite Sinus Balloon Catheter met all performance acceptance criteria including dimensional specifications; balloon burst pressure, joint separation force, deflation time, irrigation flow rate, and balloon cycle fatigue. The sterilization process is validated per AAMI/ANSI/ISO 11135-1: 2007 and demonstrated a sterility assurance level of 10^{-6}. The method used for sterilization validation is the overkill (half-cycle approach) in a fixed chamber. Ethylene oxide residuals were tested and meet ISO 10993-7:2008 requirements. The subject device is not tested or labeled as "non-pyrogenic". Shelf life was established per ASTM F1980-07 ASTM F88/F88M-09, ISTA 2A-11, and ASTM F2096-04 requirements.
Summary of Substantial Equivalence:	The Relieva Solo Elite Sinus Balloon Catheter is substantially equivalent to predicate device as confirmed through relevant tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acclarent, Inc.
Ms. Kim Ky
Manager, Regulatory & Clinical
1525-B O'Brien Dr
Menlo Park, CA 94025

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Re: K111254
Trade/Device Name: Relieva Solo Elite Sinus Balloon Catheter
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose, and throat manual surgical instrument
Regulatory Class: I
Product Code: LRC
Dated: July 18, 2011
Received: July 19, 2011

Dear Ms. Ky,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

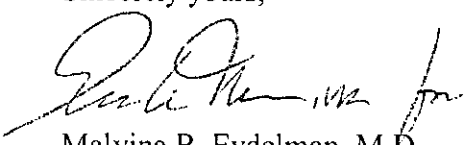
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K111254

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111254

Trade Name: *Relieva* Solo Elite Sinus Balloon Catheter

Common Name: Sinus Balloon Catheter

Indications For Use:

The Relieva Solo Elite Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

For children aged 17 and under, the Relieva Solo Elite Sinus Balloon Catheter is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111254

(Posted November 13, 2003)